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| APPLICATION NO.           | FILING DATE                                  | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------|--|----------------------|---------------------|------------------|
| 10/569,077                | 02/21/2006                                   | David S. Garvey      | 102258172US5 2613   |                  |
| 25270<br>WILMERHAI        | 25270 7590 08/24/2007<br>WILMERHALE/NITROMED |                      | EXAMINER            |                  |
| 1875 PENNSYLVANIA AVE, NW |  |                      | HAVLIN, ROBERT H    |                  |
| WASHINGTON, DC 20006      |  |                      | ART UNIT            | PAPER NUMBER     |
|                           |  |                      | 1626                |                  |
|                           |  |                      |                     |                  |
|                           |  |                      | MAIL DATE           | DELIVERY MODE    |
|                           |  |                      | 08/24/2007          | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|  |  | Application No.  | Applicant(s)  |  |  |  |
|--|--|--|---------------|--|--|--|
| Office Action Summary  |  | 10/569,077   | GARVEY ET AL. |  |  |  |
|  |  | Examiner   | Art Unit      |  |  |  |
|  |  | Robert Havlin  | 1626 ·        |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply   |  |  |               |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |  |  |               |  |  |  |
| Status   | •  |  |               |  |  |  |
| <ol> <li>Responsive to communication(s) filed on 23 May 2007.</li> <li>This action is FINAL. 2b) ☐ This action is non-final.</li> <li>Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.</li> </ol>   |  |  |               |  |  |  |
| Disposition of Claims  |  |  |               |  |  |  |
| <ul> <li>4)  Claim(s) 1-25 is/are pending in the application.</li> <li>4a) Of the above claim(s) 7-12 and 18-22 is/are withdrawn from consideration.</li> <li>5)  Claim(s) is/are allowed.</li> <li>6)  Claim(s) 1-6, 13-17, and 23-25 is/are rejected.</li> <li>7)  Claim(s) is/are objected to.</li> <li>8)  Claim(s) are subject to restriction and/or election requirement.</li> </ul>   |  |  |               |  |  |  |
| Application Papers   |  |  |               |  |  |  |
| <ul> <li>9) The specification is objected to by the Examiner.</li> <li>10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).</li> <li>11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.</li> </ul>  |  |  |               |  |  |  |
| Priority under 35 U.S.C. § 119   |  |  |               |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of: <ol> <li>Certified copies of the priority documents have been received.</li> <li>Certified copies of the priority documents have been received in Application No</li> <li>Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> </ol> </li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>   |  |  |               |  |  |  |
| Attachment   | (c)  |  |               |  |  |  |
| 1) Notice 2) Notice 3) Inform  | e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO/SB/08) · No(s)/Mail Date | 4) Interview Summary Paper No(s)/Mail Do 5) Notice of Informal P 6) Other: | ate           |  |  |  |

# **DETAILED ACTION**

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**Status of the claims**: Claims 1-25 are currently pending.

Priority: This application is a 371 of PCT/US04/26909 08/20/2004 which claims benefit of 60/496,639 (08/20/2003) and claims benefit of 60/496,722 (08/20/2003) and claims benefit of 60/496,810 (08/21/2003) and claims benefit of 60/498,291 (08/28/2003) and claims benefit of 60/498,308 (08/28/2003) and claims benefit of 60/530,643 (12/19/2003). There was no clear delineation of the subject matter of the claims and the priority documents; for example, support for formula I of claim 1 was not specifically found in the priority documents. Furthermore, the elected species was not found in the priority documents, please point to the particular page and line number where support can be found.

**IDS**: No IDS documents were submitted with this application.

#### Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 5/23/07 is acknowledged. The traversal is on the ground(s) that the examiner made a typographical error in indicating the claims of group I are 1-6, 13-17, and 23, 24, and 26, when, as the applicant points out, the claims are actually 1-6, 13-17, and 23-25 (clearly since there was no claim 26). The claims reading on the group are hereby corrected.

The requirement is still deemed proper and is therefore made FINAL. The nonelected method claims 7-12 and 18-22 are hereby withdrawn.

The applicant has elected the species of:

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The examiner notes that the applicant has failed to identify which claims read on the elected species *and* the definitions of the variable groups which read on the species as required in the restriction requirement of 5/11/2007.

# Claim Rejections - 35 USC § 112

- The following is a quotation of the second paragraph of 35 U.S.C. 112:
   The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 3. Claims 1-6, 13-17, and 23-25 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Evidence that claim 1 fail(s) to correspond in scope with that which applicant(s) regard as the invention can be found in the reply filed on 5/23/07. In that paper, applicant has stated the elected species is

invention is different from what is defined in the claim(s) because the compound does not conform to any one of formulas I-V as required by claim 1. Specifically the elected species does not correspond to any of the following genuses:

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#### **Double Patenting**

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorngton*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

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be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6, 13-17, and 23-25 are provisionally rejected on the ground of 5. nonstatutory obviousness-type double patenting as being unpatentable over claims 1,2,14,15,27-37, and 50-52 of copending Application No. 11/730,886 and claims 1,2, and 4-10 of application No. 11/705,773 and claims 54-58, 68-70, 79-90, and 99-102 of application 11/689,568 and several others that share inventors and assignee. Since there are numerous copending application which claim overlapping subject matter the applicant is required to identify any and all copending applications with related subject matter and describe how the subject matter is distinct such that it may overcome a double patenting rejection, or cancel overlapping subject matter, or file a terminal disclaimer (where appropriate and as described above in (4.)). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to the same subject matter, namely nitro derivatives of pharmaceutical agents.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

All claims are rejected.

KAMAL A. SAEED, PH.D. PRIMARY EXAMINER

PRIMARY EXAMINER

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# Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Havlin whose telephone number is (571) 272-9066. The examiner can normally be reached on Mon. - Fri., 7:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful the examiner's supervisor, Joe McKane can be reached at (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert Havlin Examiner

RH